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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,146	03/31/2005	Martin A Smith	58142(45858)	2874
21874 7590 05/16/2007 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER TUNG, JOYCE	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 05/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/530,146

Applicant(s)

SMITH ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 and 66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948).  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>8/10/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The applicant's preliminary amendment filed 3/31/07 has been entered. Claims 1-35 and 66 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 3, 11, 21, and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 3, and 11 are vague and indefinite because of the phrase "substantially". It is unclear what is definition of the phrase. Clarification is required.
- b. Claim 21 is vague and indefinite because of the phrase " the nucleus" which has no antecedent basis.
- c. Claims 23-24 are vague and indefinite because of the phrase "substantially by non-ionic interaction". It is unclear what is the definition of the phrase.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-35 and 66 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (WO 00/21973, issued April 20, 2000) in view of Burgoyne (5,496,562, issued March 5, 1996).

Mitchell et al. disclose the method steps (a)-(e) as recited in instant claim 1 (See pg. 2, third paragraph) and the method steps as recited in claim 4 (See pg. 2, third paragraph). The nucleic acid is retained by the filter substantially in the absence of ionic interaction (See column 2, last paragraph), and by physically retarding the movement of the nucleic acid down the filter (See pg. 3, first paragraph). The nucleic acid is heated to an elevated temperature, whilst retained by the filter prior to elution and the temperature is about 90°C, (See pg. 3, second paragraph, pg. 6, first paragraph, pg. 12, first paragraph and pg. 25, experiment 6). There is a solution for rupturing intact whole cells to leave condensed nuclear material and a lysis solution for lysing nuclear material (See pg. 3, third paragraph). The sample comprises whole blood, which has been treated with a red blood cell lysis solution, whilst the white cells containing the nucleic acid are retained by the filter as a retentate (See pg. 6, third paragraph). A filter material is selected which provides no barrier to cells, but enables the cells to be retained by the filter as a

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retentate (See pg. 6, second paragraph). The pore size of the filter is 4.5um (See pg. 11, table1). The filter used in the method comprises a plurality of fibers and has a substantially disordered structure, the fiber diameters are selected from the range of 1um to 10 um (See pg. 9, fourth paragraph). The fiber is glass fiber, silica based or plastic based fiber (See pg. 10, first paragraph). It is possible to isolate nucleic acid in the absence of a chaotrope (See pg. 10, second paragraph). Genomic DNA is a desired target or nucleic acid is RNA (See pg. 15, fourth paragraph).

Mitchell et al. do not disclose the method steps (f)-(g) as recited in instant claim 1.

Burgoyne discloses that the blood-stained paper was dried, and sent through the ordinary mail so that it spent at least three days in the mail, and had the DNA extracted from it (See column 4, lines 41-45). A card loaded with a DNA sample is air dried at room temperature (See column 5, lines 43-44).

Mitchell et al. do not explicitly disclose the pore size, which is from about 0.2 um to about 2.7 um as recited in claim 13.

However, the phrase "about" is not defined. The pore size such as 4.5 um as disclosed by Mitchell et al. is interpreted to fall within the range as recited in claim 13. Thus, the teachings of Mitchell et al. satisfy with the limitations of the claims.

One of ordinary skill in the art would have been motivated to apply the method steps of drying the solid phase medium with the cell lysate comprising nucleic acid and storing the dried solid phase medium with the nucleic acid because it would have been useful for long time storage, such as 36 months (See column 4, lines 21-25) or four years (See column 5, lines 1-4). It

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would have been prima facie obvious to apply the method steps (f)-(g) as recited in instant claim 1.

### Summary

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Joyce Tung *J. Tung*  
May 5, 2007

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

*5/14/07*